AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (previously presented): A process for preparing an oral fast-melt pharmaceutical composition, the process comprising:

(a) a step of wet granulating a drug in an amount of about 15% to about 75% by weight of the composition together with a liquid binding agent comprising a saccharide having high moldability,

(b) a step of blending with the drug a saccharide having low moldability, and

(c) a step for inhibiting agglomeration of the drug,

wherein steps (a), (b), and (c) occur in any order or simultaneously to result in formation of granules, wherein the drug has at least one property conferring upon the drug a tendency to agglomerate in the composition and wherein the drug is celecoxib.

Claim 2 (original): The process of Claim 1 wherein said step (b) occurs prior to or simultaneously with said step (a).

Claim 3 (original): The process of Claim 1 wherein said wet granulating step comprises fluid bed granulation.

Claims 4-9 (cancelled).

Claim 10 (original): The process of Claim 1 wherein said saccharide having low moldability is selected from the group consisting of lactose, mannitol, glucose, sucrose and xylitol.

Claim 11 (original): The process of Claim 1 wherein said saccharide having low moldability is mannitol of powder grade.

Claim 12 (original): The process of Claim 1 wherein said saccharide having high moldability is selected from the group consisting of maltose, maltitol, sorbitol and oligosaccharides having 2 to 6 monosaccharide residues.

Claim 13 (original): The process of Claim 1 wherein said saccharide having high moldability is maltose.

Claims 14-17 (cancelled).

Claim 18 (previously presented): The process of Claim 91 wherein said wetting agent is added in a total amount of about 0.05% to about 5% by weight of the composition.

Claim 19 (previously presented): The process of Claim 91 wherein said wetting agent is added in a total amount of about 0.075% to about 2.5% by weight of the composition.

Claim 20 (previously presented): The process of Claim 91 wherein said wetting agent is added in a total amount of about 0.25% to about 1% by weight of the composition.

Claim 21 (previously presented): The process of Claim 1 wherein the agglomeration inhibiting step comprises addition of at least one glidant.

Claim 22 (previously presented): The process of Claim 21 wherein said at least one glidant is silicon dioxide and/or talc.

Claim 23 (previously presented): The process of Claim 21 wherein said at least one glidant is added in a total amount of about 0.05% to about 5% by weight of the composition.

Claim 24 (previously presented): The process of Claim 21 wherein said at least one glidant is added in a total amount of about 0.1% to about 2% by weight of the composition.

Claim 25 (previously presented): The process of Claim 21 wherein said at least one glidant is added in a total amount of about 0.25% to about 1% by weight of the composition.

Claims 26-27 (cancelled).

Claim 28 (previously presented): The process of Claim 1 wherein said drug is present in an amount of about 30% to about 75% by weight of the composition.

Claim 29 (previously presented): The process of Claim 1 wherein said drug is present in an amount of about 45% to about 75% by weight of the composition.

Claim 30 (original): The process of Claim 1 wherein said saccharide having high moldability is present in a total amount of about 1% to about 10% by weight of the composition.

Claim 31 (original): The process of Claim 1 wherein said saccharide having high moldability is present in a total amount of about 1% to about 7.5% by weight of the composition.

Claim 32 (original): The process of Claim 1 wherein said saccharide having high moldability is present in a total amount of about 1% to about 5% by weight of the composition.

Claim 33 (original): The process of Claim 1 wherein said saccharide having low moldability is present in a total amount of about 10% to about 90% by weight of the composition.

Claim 34 (original): The process of Claim 1 wherein said saccharide having low moldability is present in a total amount of about 15% to about 60% by weight of the composition.

Claim 35 (original): The process of Claim 1 wherein said saccharide having low moldability is present in a total amount of about 25% to about 50% by weight of the composition.

Claim 36 (original): The process of Claim 1 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 2:100 to about 20:100.

Claim 37 (original): The process of Claim 1 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 10:100.

Claim 38 (original): The process of Claim 1 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 7.5:100.

Claim 39 (previously presented): The process of Claim 1, further comprising

(d) a step of blending said granules with at least one of a lubricant, a sweetening agent and a flavoring agent to form a tableting blend, and

(e) a step of compressing the tableting blend to form oral fast-melt tablets.

Claim 40 (previously presented): The process of Claim 39 wherein parameters are set in said compressing step (e) to provide tablets having a hardness of about 1 to about 10 kp.

Claim 41 (currently amended): An oral fast-melt pharmaceutical composition prepared by the process of any of Claims 1**-3, 10-13, 18-25, and 28-40** ~~through 40~~.

Claim 42-45 (cancelled).

Claim 46 (previously presented): The composition of Claim 101 wherein said wetting agent, if present, is present in an amount of about 0.05% to about 5% by weight of the composition.

Claim 47 (previously presented): The composition of Claim 100 wherein said wetting agent, if present, is present in an amount of about 0.075% to about 2.5% by weight of the composition.

Claim 48 (previously presented): The composition of Claim 100 wherein said wetting agent, if present, is present in an amount of about 0.25% to about 1% by weight of the composition.

Claim 49 (cancelled).

Claim 50 (previously presented): The composition of Claim 96 wherein said glidant, if present, is silicon dioxide and/or talc.

Claim 51 (currently amended): The composition of Claim **90** **[[49]]** wherein said glidant**, if present,** is present in an amount of about 0.05% to about 5%.

Claim 52 (currently amended): The composition of Claim **90** **[[49]]** wherein said glidant**, if present,** is present in an amount of about 0.1% to about 2%.

Claim 53 (currently amended): The composition of Claim **90** **[[49]]** wherein said glidant**, if present,** is present in an amount of about 0.25% to about 1%.

Claims 54-61 (cancelled).

Claim 62 (previously presented): The composition of Claim 99 wherein said drug is present in an amount of about 30% to about 75% by weight of the composition.

Claim 63 (previously presented): The composition of Claim 99 wherein said drug is present in an amount of about 45% to about 75% by weight of the composition.

Claim 64 (previously presented): The composition of Claim 99 wherein said saccharide having low moldability is selected from lactose, mannitol, glucose, sucrose and xylitol.

Claim 65 (previously presented): The composition of Claim 99 wherein said saccharide having low moldability is present in an amount of about 10% to about 90% by weight of the composition.

Claim 66 (previously presented): The composition of Claim 99 wherein said saccharide having low moldability is present in an amount of about 15% to about 60% by weight of the composition.

Claim 67 (previously presented): The composition of Claim 99 wherein said saccharide having low moldability is present in an amount of about 25% to about 50% by weight of the composition.

Claim 68 (previously presented): The composition of Claim 99 wherein said saccharide having low moldability is mannitol of powder grade.

Claim 69 (previously presented): The composition of Claim 99 wherein said saccharide having high moldability is selected from the group consisting of maltose, maltitol, sorbitol and oligosaccharides having 2 to 6 monosaccharide residues.

Claim 70 (previously presented): The composition of Claim 99 wherein said saccharide having high moldability is maltose.

Claim 71 (previously presented): The composition of Claim 99 wherein said saccharide having high moldability is present in an amount of about 1% to about 10% by weight of the composition.

Claim 72 (previously presented): The composition of Claim 99 wherein said saccharide having high moldability is present in an amount of about 1% to about 7.5% by weight of the composition.

Claim 73 (previously presented): The composition of Claim 99 wherein said saccharide having high moldability is present in an amount of about 1% to about 5% by weight of the composition.

Claim 74 (previously presented): The composition of Claim 99 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 2:100 to about 20:100.

Claim 75 (previously presented): The composition of Claim 99 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 10:100.

Claim 76 (previously presented): The composition of Claim 99 wherein the weight ratio of said saccharide having high moldability to said saccharide having low moldability is about 5:100 to about 7.5:100.

Claim 77 (previously presented): The composition of Claim 99 that is in the form of a tablet.

Claim 78 (previously presented): The composition of Claim 77 wherein said tablet disintegrates within about 30 to about 300 seconds in a standard in vitro disintegration assay.

Claim 79 (previously presented): The composition of Claim 77 wherein said tablet disintegrates within about 30 to about 200 seconds in a standard in vitro disintegration assay.

Claim 80 (previously presented): The composition of Claim 77 wherein said tablet disintegrates within about 30 to about 150 seconds in a standard in vitro disintegration assay.

Claim 81 (previously presented): The composition of Claim 77 wherein said tablet disintegrates within about 5 to about 60 seconds after placement in the oral cavity of a subject.

Claim 82 (previously presented): The composition of Claim 77 wherein said tablet disintegrates within about 5 to about 30 seconds after placement in the oral cavity of a subject.

Claim 83 (previously presented): The composition of Claim 77 wherein said tablet disintegrates within about 5 to about 25 seconds after placement in the oral cavity of a subject.

Claims 84-85 (cancelled).

Claim 86 (previously presented): A method of treating a medical condition or disorder in a mammalian subject where treatment with a cyclooxygenase-2 inhibitor is indicated, comprising orally administering to the subject a composition of Claim 99.

Claim 87 (original): The method of Claim 86 wherein said mammalian subject is a human subject.

Claim 88 (original): The method of Claim 87 that further comprises combination therapy with one or more drugs selected from the group consisting of opioids and other analgesics.

Claim 89 (original): The method of Claim 87 that further comprises combination therapy with an opioid compound selected from the group consisting of codeine, meperidine, morphine and derivatives thereof.

Claim 90 (previously presented): The process of Claim 1 wherein said agglomeration inhibiting step comprises (i) adding to the composition at least one inhibitory agent selected from the group consisting of wetting agents and glidants and/or (ii) pre-wetting the drug prior to step (a).

Claim 91 (previously presented): The process of Claim 1 wherein said agglomeration inhibiting step comprises adding to the composition at least one wetting agent.

Claim 92 (previously presented): The process of Claim 91 wherein the at least one wetting agent is selected from the group consisting of surfactants, hydrophilic polymers, and clays.

Claim 93 (previously presented): The process of Claim 91 where the at least one wetting agent comprises at least one surfactant.

Claim 94 (previously presented): The process of claim 93 wherein the at least one surfactant is selected from the group consisting of quaternary ammonium compounds, dioctyl sodium sulfosuccinate, polyoxyethylene alkylphenyl ethers, polyoxyethylene fatty acid glycerides and oils, polyoxyethylene alkyl ethers, polyoxyethylene fatty acid esters, polyoxyethylene sorbitan esters, propylene glycol fatty acid esters, sodium lauryl sulfate, fatty acids and salts thereof, glyceryl fatty acid esters, sorbitan esters, and tyloxapol.

Claim 95 (previously presented): The process of Claim 93 where the at least one surfactant comprises sodium lauryl sulfate.

Claim 96 (previously presented): The composition of Claim 99 wherein said agglomeration inhibiting means comprises at least one wetting agent and/or at least one glidant.

Claim 97 (previously presented): The process of Claim 1 wherein the drug is dispersed in the composition.

Claim 98 (previously presented): The process of Claim 1 wherein said at least one property is selected from the group consisting of electrostatic, cohesive, low bulk density, low compressibility, and poor flow.

Claim 99 (previously presented): An oral fast-melt composition comprising:

(a) a drug in an amount of about 15% to about 75% by weight of the composition;

(b) a liquid binding agent comprising a saccharide having high moldability; and

(c) a means for inhibiting agglomeration of the drug;

wherein the drug is uniformly dispersed in the liquid binding agent, wherein the drug has at least one property conferring upon the drug a tendency to agglomerate, and wherein the drug is celecoxib.

Claim 100 (previously presented): The composition of Claim 99 wherein said at least one property is selected from the group consisting of electrostatic, cohesive, low bulk density, low compressibility, and poor flow.

Claim 101 (previously presented): The composition of Claim 99 wherein the inhibiting means comprises a wetting agent.

Claim 102 (currently amended): The composition of Claim **101** **[[99]]** wherein the at least one wetting agent is selected from the group consisting of surfactants, hydrophilic polymers, and clays.

INTERVIEW SUMMARY UNDER 37 CFR §1.133

On October 23, 2003, Examiner Tran graciously conducted an interview with James Forbes and Kenton Fedde ("Interviewers"), respectively Applicants' agent and attorney. The subject of the interview was the amendment filed on September 22, 2003 in response to the Office action dated March 20, 2003. No Office action responsive to the September 22, 2003 amendment had been prepared at the time of the interview.

During the interview, Examiner Tran indicated that Claim 102, as shown in the September 22, 2003 amendment, improperly depended from Claim 99 and could be made properly dependent from Claim 101. In addition, Interviewers discussed the amendment to Claim 1 presented in the September 22, 2003 amendment and reviewed with Examiner Tran the remarks submitted with the amendment. Specifically, Interviewers pointed out that:

1. the phrase "a step for inhibiting agglomeration of the drug" in Claim 1 satisfies the requirements of 35 U.S.C. §112, paragraph 6;
2. according to Carroll Touch, Inc. v. Electro Mechanical Sys., 15 F.3d 1573, 27 U.S.P.Q.2d 1836 (Fed. Cir. 1993), to anticipate Claim 1, a prior art reference would have to, *inter alia*, teach both the structure and function of the §112, paragraph 6 phrase; and
3. none of the references cited in the March 20, 2003 Office action (i.e., Mizumoto et al., U.S. Pat. No. 5,576,014 ("Mizumoto"); Talley et al., U.S. Pat. No. 5,760,068 ("Talley"); and Jain et al., U.S. Pat. No. 6,316,029 ("Jain")) disclose or describe the use of an agglomeration inhibitor having the function of inhibiting agglomeration of a drug having a tendency to agglomerate.

In her Interview Summary, Examiner Tran reiterated point 2 above.